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530 7590 05/13/2008 LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090				
EXAMINER LEAVITT, MARIA GOMEZ				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Election/Restrictions

Applicant's election of Group II drawn to claims 12-29, 39, 40, 41, and 42-46 in the reply filed on 02-04-2008 is acknowledged. However, Applicant has neglected to elect one specific species as required in the restriction requirements filed on 12-12-2007 from the following species:

Species restriction

Should Groups II be elected, a species restriction is further required under 35 U.S.C. 121 and 372, wherein a species election(s) must correspond to an elected group as indicated above.

1) A genus of molecules as recited in claim 15 selected from one of the following molecules:

cationic lipids, cationic polymers, lysophospholipides and polypeptides.

The species are independent or distinct because there are **substances** having different chemical structures, physical properties, and biological functions. Thus, the combined features of a particular species, distinct structurally and functionally, would not necessarily overlap with one another when a prior art search is conducted.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1, 12, and 35 are generic.

2) A genus of molecules as recited in claim 22 selected from one of the following molecules:

E1, E2, E4 and LI-L5 regions of the adenoviral genome.

The species are independent or distinct because there are **deletions within the adenoviral genome** having different chemical structures, physical properties, and biological functions as the result of having different expressed genes. Thus, the combined features of a particular species, distinct structurally and functionally, would not necessarily overlap with one another when a prior art search is conducted.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1, 12, and 35 are generic.

3) A genus of molecules as recited in claim 17 selected from one of the following molecules:

Deletion I, II, III, IV, V and VI of the MVA genome

The species are independent or distinct because there are **deletions within the MVA genome** having different chemical structures, physical properties, and biological functions as the result of having different expressed genes. Thus, the combined features of a particular species, distinct structurally and functionally, would not necessarily overlap with one another when a prior art search is conducted.

4) A genus of molecules as recited in claims 25 and 26 selected from one of the following molecules:

interleukins IL-2, IL-4, IL-7, IL-10 and IL-12, interferons, tumor necrosis factor (TNF), colony stimulating factors (CSF), IL-2 and INF γ

The species are independent or distinct because there are **molecules** having different chemical structures, physical properties, and biological functions as the result of having different

expressed genes. Thus, the combined features of a particular species, distinct structurally and functionally, would not necessarily overlap with one another when a prior art search is conducted.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1, 12, and 35 are generic.

5) A genus of molecules as recited in claims 42 and 47 selected from one of the following molecules:

IL-2 and INF γ

The species are independent or distinct because there are **molecules** having different chemical structures, physical properties, and biological functions as the result of having different expressed genes. Thus, the combined features of a particular species, distinct structurally and functionally, would not necessarily overlap with one another when a prior art search is conducted.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1, 12, and 35 are generic.

Should Groups II or III be elected, a species restriction is further required under 35 U.S.C. 121 and 372, wherein a species election(s) must correspond to an elected group as indicated above.

6) A genus of vectors as recited in claim 14 selected from one of the following:

Plasmid and viral vectors.

The species are independent or distinct because there are **vectors** having different chemical structures, physical properties, and biological functions as the result of having different expressed genes. Thus, the combined features of a particular species, distinct structurally and functionally, would not necessarily overlap with one another when a prior art search is conducted.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1, 12, and 35 are generic.

If applicant elect a viral vector, a further selection of species is required from the following vectors:

7) A genus of vectors as recited in claim 16 selected from one of the following:
a pox virus, from an adenovirus, from a retrovirus, from a herpes virus, from an alphavirus, from a foamyvirus or from an adenovirusassociated virus.

The species are independent or distinct because there are **viruses** having different chemical structures, physical properties, and biological functions as the result of having different expressed genes. For example both an adenovirus and pox viruses are DNA viruses; however there are functionally different, for example, adenovirus vectors are advantageously used to efficiently infect most cell types, whereas pox virus can adventurously insert large sizes of DNA. Thus, the combined features of a particular species, distinct structurally and functionally, would not necessarily overlap with one another when a prior art search is conducted.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1, 12, and 35 are generic.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1, 12, and 35 are generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and identification of the claims encompassing the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be

considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Since the above-mentioned reply appears to be *bona fide*, applicant is given **ONE (1) MONTH or THIRTY (30) DAYS** from the mailing date of this notice, whichever is longer, within which to supply the omission or correction in order to avoid abandonment. **EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136(a).**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria Leavitt whose telephone number is 571-272-1085. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1633

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

/Maria Leavitt/

Maria Leavitt, PhD
Examiner, Art Unit 1633